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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,705	07/26/2001	Brad T. Bosworth	21419/91512	2430

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EXAMINER
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WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

<b>Office Action Summary</b>	<b>Application No.</b> 09/844,705	<b>Applicant(s)</b> BOSWORTH ET AL.	
	<b>Examiner</b> Joseph T. Voitach	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☒ Claim(s) 3-5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This application filed April 27, 2001 is a continuation of 09/443,766 filed November 19, 1999, which claims benefit under 35 U.S.C. 120 to PCT/US98/10318, filed May 20, 1998, which claims benefit to provisional application 60/047,181, filed May 20, 1997.

The preliminary amendment filed July 26, 2001, paper number 7, has been received but not entered. The amendments to the specification indicated in the preliminary amendment could not be entered because they were not consistent with the specification in the file. The amendment has been placed in the file but not entered. Applicants amendment filed June 27, 2003, paper number 9, has been received and entered. The specification has been amended. Claims 1 and 2 have been canceled. Claims 3- 6 have been added. Claims 3-6 are pending and currently under examination.

### ***Priority***

This application has been indicated to be a divisional of Application No. 09/443,766, filed November 19, 1999. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." In this case this application discloses and claims only subject matter disclosed in prior Application No.

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09/443,766, now US Patent 6,596,923 and names an inventor or inventors named in the prior application. Accordingly, this application would constitute a continuation.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Specifically, on page 20, a listing of references cited has been set forth, however no copy of the references have been provided, nor has an IDS been filed.

***Oath/Declaration***

It is noted that copies of two separate declarations have been filed and are present in the file. Consistent with the declarations filed in 09/443,766, one copy contains alterations which have not been initialed. The substitute declarations that were subsequently filed June 28, 2001, are in compliance with 37 CFR 1.67.

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### ***Claims***

Claims 3-5 are objected to because of the following informalities: the claims recite “ECF18R”, however this term is not specifically defined in the claim or the specification. It is noted that there is general support in the specification for the designation for a gene locus (page 7, line 22). When not specifically defined in the specification, the first presentation of an abbreviated term should be denoted by setting forth the full name indicating the term to be used subsequently.

Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying swine which are resistant to *E. coli* strain F18 associated intestinal disorders, said method comprising: a) providing a biological sample from a swine; b) determining the polynucleotide at position 307 of the open reading of alpha (1,2) fucosyltransferase gene (FUT1)(SEQ ID NO: 12), whereby the identification of an adenine at said position on both alleles of the swine is associated with swine which are resistant to *E. coli* strain F18 colonization; and c) identifying swine with an adenine at position 307 of the open reading of

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FUT1 gene as resistant to *E. coli* strain F18 associated intestinal disorders, and methods of using said identified swine for breeding, does not reasonably provide enablement for identifying an adenine at other positions within the FUT1 gene or for intestinal disorders associated with other *E. coli* strains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification teaches that it was observed that certain swine were resistant to intestinal disorders, in particular they were resistant to problems associated with *E. coli* colonization. Furthermore, as exemplified by Merjerink *et al.* and Vogeli *et al.* and supported by the specification it has been demonstrated that the presence of the homozygous FUT1 allele represented by an adenine at position 307 of the open reading of FUT1 is associated with resistance to *E. coli* strain F18 associated intestinal disorders. Importantly, the specification only provides only this single specific alteration in the FUT1 allele and its association with only *E. coli* strain F18. It may be that other strains of *E. coli* strains can cause intestinal disease associated with colonization, however as noted by Bertin *et al.* and Duchet-Suchaux *et al.*, resistance of a swine to one strain of *E. coli* does not indicate resistance to other strains of *E. coli*. Thus, the presence of resistance to one strain of *E. coli*, is not, *a priori*, predictive of resistance to other strains of *E. coli*. In this case the basis for the observed resistance in swine associated with the specific alteration in the FUT1 allele is not known. Absent evidence that the polymorphism results in a mechanistic reason for the resulting resistance, a genetic marker/polymorphism is

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simply a marker which can be associated with a specific characteristic. For example, the specification defines several other polymorphism in coding regions of the FUT1 and FUT2 genes, however none of these polymorphism are associated with any resistance to *E. coli* or any other observable phenotype. There is no evidence that the polymorphism itself results in the phenotype, therefore the adenine at position 307 of the open reading of FUT1 gene represents only a marker for the phenotypic observation of a swine resistance to F18 *E. coli*.

In the instant case, Applicants have shown a correlation with the presence of a homozygous polymorphism at base 307 in the open reading frame of the FUT1 gene and a resistance to F18 and thus, absence of the associated diseases. However, the mechanism of this resistance is not known nor described. Even post filing art, Merjerink *et al.* (Mammalian Genomics 8:736-741), including one of the inventors-Vogeli, clearly indicates that the mechanism of the resistance was unknown at the time of the claimed invention (summarized in final sentence of abstract). Therefore, at the time of the invention made, the observation of the polymorphism associated with F18 resistance represents only a correlative analysis linking a specific phenotype with a specific polymorphism and would not necessarily be extended to resistance to other strains of *E. coli*.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required one of skill in the art undue experimentation to practice the invention as claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically,

Claims 3-5 are unclear in the recitation of 'at position 307 in the open reading frame of the alpha (1,2) fucosyltransferase gene 1' because it is not clear to the exact position in what gene the claim refers, the genomic sequence (coding or noncoding), the complete translated RNA, or only the open reading frame. Clarification by reciting a specific SEQ ID NO or specific reference to a specific sequence is suggested. In addition, the claim is unclear because it lacks a critical step of how the sequence is determined. In light of the specification, various molecular methodology can be used to determine the specific base pair, or more generally the resistance of the swine's cells to colonization to infection can be used. Clarification by recitation of an additional step on of how the identity of the base is determined and an interpretation of the result is suggested. Claim 6 is included in the rejection because it fails to further clarify the basis of the rejection.

Claims 3-5 are unclear and confusing in the recitation of "ECF18R" The term is not specifically defined in the claim nor the specification. It is noted that here is general support



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in the specification for the designation for a gene locus (page 7, line 22), however within the context of the claimed method this would be confusing because *E. coli* do not bind genes.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(f) he did not himself invent the subject matter sought to be patented.

Claims 3-6 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant application and US Patent 6,355,859 share one common inventor and no common assignee. Each specification discloses that an adenine at position 307 of the open reading frame of the FUT1 gene is associated with resistance to F18 *E. coli* in swine. In addition, each application teaches that the artisan can use this association of F18 *E. coli* resistance for identification and possible treatment of swine suffering from effects of *E. coli* colonization, and have similar pending claims (though in the instant application, these methods are withdrawn from consideration as be drawn to a non-elected invention, i.e. claims 3 and 8). In light of the very similar teachings and claims in each application, the contribution of the different inventive entity for each application is unclear. Clarification of each Inventors contribution to the instant invention, and/or amendment of inventorships is required.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,355,859. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant application, claims are drawn to a method for identifying a swine that is resistant to intestinal colonization to a of strain of *E. coli* associated intestinal disorders by determining whether base pair 307 of the open reading frame of FUT1 is an adenine, and in particular the *E. coli* is strain ECF18R. In '859 claim 4, which dependent on claim 1, is drawn to a method for controlling weight in a swine by determining whether a swine is genetically resistant to F18 *E. coli* colonization by determining base pair 307 of the open reading frame of FUT1 is an adenine. It is well known in the art that colonization of specific strains of *E. coli*,

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such as F18, result in severe diarrhea and result in weight loss. Practicing the method encompassed by claims 3 and 4 in the instant application results in identifying a swine which is resistant to F18 *E. coli* colonization and the resulting symptoms associated with said colonization and therefore, would make obvious the identification a swine capable of more controlled weight gain in a herd generally susceptible to F18 *E. coli* colonization. Practicing the method encompassed by claims 3 and 4 of the instant specification would anticipate the method and results accomplished in claims 1 and 4 in '859.

Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,596,923. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In this case the method of '923 would anticipate the instantly claimed methods set forth in claims 3 and 4 because in each case a alteration/mutation if the FUT1 gene is being identified. Moreover, the mutation/alteration in the FUT1 gene is associated with decreased intestinal disorders. Claim 5 comprises practicing the methods set forth in claims 3 and 4 and provides an additional step of mating the identified swine for the implicit intention of obtaining additional or more pure bread swine with the particular genotype that is associated with the desired phenotype of being more resistant to intestinal disorders associated with *E. coli*. Claim 6 specifically sets forth that the *E. coli* is strain F18, which is specifically set forth in claim 1 of '923. Claims 5 and

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6 are included in this rejection because they would be considered an obvious step of practicing the method set forth in claim 1 (also of claims 3 and 4) as set forth in step (a) of claim 5.

### ***Conclusion***

No claim is allowed. The claims are free of the art of record. The art indicates that cell surface receptors on intestinal cells are the target molecules for *E. coli* colonization, and that the glycosylation on said receptors may be important in determining the ability of a particular *E. coli* to colonize the intestine. However, the art fails to specifically teach that an adenine at position 307 of the open reading frame of alpha (1,2) fucosyltransferase (FUT1) (SEQ ID NO: 12) can be correlated with resistance to *E. coli* strain F18 and possibly with the subsequent associated diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach